K050996

MAY - 5 2005

510(k) Summary for the O-Arm™ Imaging System (4/01/05)

Submittal information:

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Device name and classification

Proprietary Name: O-Arm™ Imaging System
Classification Names: Mobile X-ray System, Solid-state X-ray Imager
Classification Panel: Radiology
CFR Sections: 21 CFR 892.1720, 21 CFR 892.1650
Class: II
Product Codes: OXO

Substantial Equivalence

The O-Arm™ Imaging System is substantially equivalent to the Siemens SIREMOBIL
Iso-C^{3D}, which was cleared in 510(k)'s K032280 and K003266.

Device Description

The O-Arm™ Imaging System is a mobile x-ray system which provides 3D imaging as well as 2D fluoroscopic imaging.

The system consists of two parts: the x-ray O-Arm™ Stand (comprising x-ray generator, flat dynamic x-ray detector, and the x-ray control user interface) and the mobile view station (comprising the image processors, a user interface for image and patient handling, and viewing monitors).

Intended Use

The O-Arm™ Imaging System is designed for 2D Fluoroscopic and 3D imaging for intraoperative applications in surgical theaters, particularly for orthopedic applications. The O-Arm™ Imaging System is compatible with certain Image Guided Surgery Systems.

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Comparison with the Predicate Device

	O-Arm™ Imaging System	SIREMOBIL Iso C^{3D}
Physical configuration	A portable system with separate viewing station. The imaging unit is full circle or "O-arm".	A portable system with separate viewing station. The imaging unit is a 190°C-arm.
Imaging modes	3-D imaging 2-D fluoroscopy	3-D imaging 2-D fluoroscopy
Intended use	Intraoperative imaging	Intra-operative imaging.

Similarities and Differences

Both devices perform both 2-D fluoroscopy and 3-D volumetric imaging.

The mechanical configuration of both devices allows a lateral approach to the patient. The predicate device has a c-arm configuration, mounting the source and detector on distal ends of the 'C'. The O-Arm™ mounts the imaging components on a c-shaped rotor inside of an enclosed, full circle housing. The O-Arm™ housing is opened to approach the patient.

For 2-D imaging with the predicate device, the user manually orients the source and detector for the needed image trajectory. The O-arm™ utilizes high-precision robotics to orient the internal rotor to the proper trajectory. To return to a position, the Siemens user manually repositions the 'C'. With its robotic positioning, the O-arm™ automatically returns to positions "saved" by the user.

For 3-D imaging, the predicate device drives the 'C' in a circumferential movement through a 190° arc. The O-Arm™ drives the internal C-shaped rotor through a 360° arc inside the enclosed housing.

Both systems have two mobile, interconnected units: an X-ray stand and a mobile viewing station. Both units of the predicate device are moved manually. The O-Arm™ X-ray Stand has a power-assisted transport mechanism.

Both systems are configured with opposing x-ray source and x-ray detector. The sources are similar. The predicate device uses a circular image intensifier tube as the detector, while the O-Arm™ uses a rectangular flat panel digital detector. As a result, the images are displayed differently. In 2-D, the image intensifier displays a circular image, and the flat panel displays a rectangular image. In 3-D, the image intensifier reconstructs to a volumetric sphere, while the O-arm™ reconstructs to a volumetric cylinder. X-ray beam collimation, available in both systems, allow the user to select the area or volume to best fit the application.

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Assessment of Performance Data

A concurrence study was performed comparing images of the same anatomical structure made with a Siemens ISO-C C-Arm Imaging System and with the O-Arm™ Imaging System. The imaged subject was a cadaver allowing virtually identical sites to be imaged by both systems. Sites were selected to include common orthopedic procedure locations. Thirty one pairs of images, including 3-D and fluoroscopic images, were evaluated. The fluoroscopic images were evaluated "live". Both the O-Arm and the predicate device have a feature that freezes the last image of a fluoroscopic series. The 3-D images and the "frozen" last images last images were submitted with the 510(k).

A radiologist evaluated the images during the study. He determined that for all image pairs, the images from the O-Arm™ and the predicate device are of equivalent diagnostic capability.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Breakaway Imaging, LLC
% Mr. Jeff Rongero
Senior Project Engineer/Program Reviewer
Conformity Assessment Services
Underwriters Laboratories, Inc.
1285 Walt Whitman Road
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Re: K050996
Trade/Device Name: O-Arm Imaging System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image intensified fluoroscopic x-ray system, mobile
Regulatory Class: II
Product Code: OXO
Dated: April 18, 2005
Received: April 20, 2005

Dear Mr. Rongero:

This letter corrects our substantially equivalent letter of May 5, 2005.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please Note: CDRH does not evaluate information related to contact liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely Yours,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): __N/A__ K050996

Device Name: ___ O-Arm™ Imaging System____

Indications for Use:

The O-Arm™ Imaging System is designed for 2D Fluoroscopic and 3D imaging for intraoperative applications in surgical theaters, particularly for orthopedic applications. The O-Arm™ Imaging System is compatible with certain Image Guided Surgical Systems.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) ~~AND~~/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Jogerson

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K050996